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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,374

04/21/2005

Jay A Berzofsky

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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

08/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,374	Applicant(s) BERZOFSKY ET AL.	
	Examiner Sheela J. Huff	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/7/09;6/11/09;6/19/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed on 6/11/09 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 46-72 are pending.

The rejection under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's arguments.

Information Disclosure Statement

The IDS filed 8/7/09 and 6/19/09 have been considered.

The information disclosure statement filed 6/11/09 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Only the cross-off references have not been considered.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 46-50, 52-55, 59-67, 69 and 71 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dasch et al US 6090383 in view of WO 00/01410, Barbera-Guillem US 6224866, Rosenblum US 2005/0214307 (filed 3/17/95) and Zavada et al US 6297041. The reasons for this rejection are of record in the paper mailed 2/11/09.

Applicant argues that the claims are directed to a method of inhibiting a tumor recurrence not to a method of treating and provides a declaration to show that the actions of inhibiting and treating are very different and that treating cannot be equated

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to inhibiting. Applicant is under the impression that the Examiner is exclusively equating treating to inhibiting. This is not true. It is applicant's own specification that equates inhibiting to treating but as clearly discussed inhibiting is only a part of treating. As state on page 17 of the specification treating includes inhibiting. Thus a treatment can read on inhibition. In fact, the Zavada et al reference enables their treatment by showing examples of inhibition (see Examples 3-5) and in col. 8, lines 25+ shows that the treatment of patients with neoplastic diseases can be inhibited by administering the compounds of the invention. Dasch discloses that the therapeutically effective amount "inhibits" the tumor immunosuppressive growth which results in tumor regression. (col. 4, lines 15+). Rosenblum shows that the treatment of their compound is accomplished by inhibition of cell growth([0102]). Thus, the references state that treatment reads on inhibition.

Applicant also argues that the examiner has narrowly read the passage from page 16, lines 32-33 of the specification and that the intent of the passage was to be that the neutralizing antibody can be used to inhibit reoccurrence following any treatment of a tumor. This is true, but it seems applicant is implying that the antibody of the invention can only inhibit tumor recurrence after previous treatment and as shown by Dasch, which uses the same antibody as applicant, the same antibody can also be used in treatment.

The declaration also gives examples of compounds which are ineffective in treat the recurrence even though they can treat the tumor. The references cited to support this were not found and therefore the examiner cannot comment on these. However, in

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view of Rosenblum, Dasch and Zavada indicating that treatment reads on inhibition (that treatment can be enabled by showing inhibition), and in view of the fact that inhibition is a part of treatment, and since the references all indicate that compounds that treat tumors can be used in the treatment of tumor recurrence, the art still renders the claimed invention obvious.

The declaration also states that 'detection' is not equated with inhibition. This is not what the examiner stated. The reference discloses antibodies to TGF-beta and these are used in diagnosis and treatment of proliferating cells. Thus, this reference is saying that same compound can be used in the diagnosis and treatment. Furthermore, the reference states that the compounds can be used in the diagnosis of tumor recurrence. It logically follows that because compounds that can be used in the diagnosis and the treatment of tumors and can also be used in the diagnosis of tumor recurrence, one would immediately envisage that the compounds that can be used in the diagnosis of tumor recurrence can also be used in the treatment of tumor recurrence. The examiner is not equating detection with inhibition, the examiner is saying that is known to be used in treatment and diagnosis of tumors and known to be used in the diagnosis of tumor recurrence, one skilled in the art would logically envisage the treatment of tumor recurrence.

Applicant also argues each reference individually. This is not persuasive because it is the combination of the references that makes applicant's invention obvious and the combination of the references has been discussed, argued and responded to above.

Claims 46-55, 59-72 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dasch et al US 6090383 in view of WO 00/01410, Barbera-Guillem US 6224866, Rosenblum US 2005/0214307 (filed 3/17/95) and Zavada et al US 6297041 and Suthanthiran et al US 2004-0197333 (filed 2/10/00). The reasons for this rejection are of record in the paper mailed 2/11/09.

Applicant's arguments have been addressed above.

Claims 46-72 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dasch et al US 6090383 in view of WO 00/01410, Barbera-Guillem US 6224866, Rosenblum US 2005/0214307 (filed 3/17/95) and Zavada et al US 6297041 and Terabe et al Nature Immunology vol. 1 p. 515 (12/00). The reasons for this rejection are of record in the paper mailed 2/11/09.

Applicant's arguments have been addressed above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dasch et al J. Immunol. Vol. 142 p. 1536 (1989).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Monday-Thursday 6am to 2pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sheela J Huff/
Primary Examiner
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sjh